CLAIMS

What is claimed is:

1. A method for planning a stability study of a pharmaceutical composition comprising:

   a) selecting a value for a release limit variable for a given specification test;
   b) selecting a desired length of the shelf-life of said pharmaceutical composition;
   c) selecting a time at which an analysis of the data for said stability study will be performed;
   d) selecting time points at which one or more measurements of one or more predetermined pharmaceutical test variables will be performed;
   e) selecting a number of measurements of said predetermined test variables that will be performed at each of said time points;
   f) selecting a value for the expected degradation rate of said pharmaceutical composition over time;
   g) selecting a value for the intermediate precision of said measurements; and
   h) selecting a probability level regarding the level of certainty of the outcome of said stability study.

2. The method of claim 1 wherein the selected value of said expected degradation rate is based on previous long-term stability studies.

3. The method of claim 1 further comprising calculating the shelf-life specification limits of said pharmaceutical composition based upon the variables selected in steps a) through h).

4. The method of claim 3 further comprising optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation.

5. The method of claim 3 wherein the specification test limits are re-calculated by substituting in actual data obtained during said stability study for one or more of the variables selected in steps a) through h).

6. The method of claim 5 further comprising optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation.

7. The method of claim 6 wherein said probability level regarding the level of certainty is at least 95%.

8. The method of claim 1 wherein said probability level is at least 90%.

9. The method of claim 1 wherein said probability level is 95 %.

10. The method of claim 1 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition in alternate formulations.

11. The method of claim 1 wherein the selected value of said expected degradation rate is based on previous accelerated stability studies of said pharmaceutical composition.

12. The method of claim 11 wherein the selected value is based on accelerated stability results that are temperature corrected by the Arrhenius formula.

13. The method of claim 1 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

14. The method of claim 1 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous accelerated stability studies of said pharmaceutical composition.

15. The method of claim 1 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition while the

selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from conducting a stability study of said pharmaceutical composition.

16. The method of claim 1 wherein the selected value of said expected degradation rate is based on conducting a stability study of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

17. The method of claim 1 wherein the time points for measurement of the variables selected in steps a) through h) are at 0, 3, 6, 9, and 12 months after start of the stability study of said pharmaceutical composition.

18. The method of claim 1 wherein the shelf-life specification limits of said pharmaceutical composition is calculated utilizing the Allen Formula.

19. The method of claim 1 wherein the shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the probability level of said pharmaceutical composition satisfying its specification tests is at least 95%.

20. The method of claim 1 wherein said pharmaceutical composition is administered through an oral administration of a pharmaceutical formulation such as a tablet.

21. The method of claim 20 wherein said tablet varies in physical size.

22. The method of claim 20 wherein the packaging for said pharmaceutical formulation varies.

23. The method of claim 20 wherein the dosage strength of an active ingredient in said tablet varies.

24. A method of determining shelf-life specifications of pharmaceutical composition, comprising:

a) selecting a value for a release limit variable for a given specification test;

b) selecting a desired length of the shelf-life of said pharmaceutical composition;

c) selecting a time at which an interim analysis will be performed;

d) selecting time points at which one or more measurements of one or more predetermined pharmaceutical test variables will be performed;

e) selecting a number of measurements of said predetermined test variables that will be performed at each of said time points;

f) selecting a value for the expected degradation rate of said pharmaceutical composition over time;

g) selecting a value for the intermediate precision of said measurements; and

h) selecting a probability level regarding the level of certainty of the outcome of said stability study; and

i) calculating the shelf-life specification limits of said pharmaceutical composition based upon the variables selected in steps a) through h).

25. The method of claim 24 wherein said probability level regarding the level of certainty is at least 90%.

26. The method of claim 24 further comprising optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation.

27. The method of claim 24 wherein the selected value of said expected degradation rate is based on previous long-term stability studies.

28. The method of claim 24 wherein the specification test limits are re-calculated by substituting in actual data obtained during said stability study for one or more of the variables selected in steps a) through h).

29. The method of claim 24 wherein said probability level is at least 95%.

30. The method of claim 24 wherein said probability level is 99 %.

31. The method of claim 24 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition in alternate formulations.

32. The method of claim 24 wherein the selected value of said expected degradation rate is based on previous accelerated stability studies of said pharmaceutical composition.

33. The method of claim 24 wherein the selected value is based on accelerated stability results that are temperature corrected by the Arrhenius formula.

34. The method of claim 24 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

35. The method of claim 24 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous accelerated stability studies of said pharmaceutical composition.

36. The method of claim 24 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from conducting a stability study of said pharmaceutical composition.

37. The method of claim 24 wherein the selected value of said expected degradation rate is based on conducting a stability study of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

38. The method of claim 24 wherein the time points for measurement of the variables selected in steps a) through h) are at 0, 3, 6, 9, and 12 months after start of the stability study of said pharmaceutical composition.

39. The method of claim 24 wherein the shelf-life specification limits of said pharmaceutical composition is calculated utilizing the Allen Formula.

40. The method of claim 24 wherein the shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the probability level of said pharmaceutical composition satisfying its specification tests is at least 90%.

41. The method of claim 24 wherein said pharmaceutical composition is administered through an oral administration of a pharmaceutical formulation such as a tablet.

42. The method of claim 41 wherein said tablet varies in physical size.

43. The method of claim 41 wherein the packaging for said pharmaceutical formulation varies.

44. The method of claim 41 wherein the dosage strength of an active ingredient in said tablet varies.

45. A method for planning a stability study of a pharmaceutical composition comprising:

a) selecting a value for a release limit variable for a given specification test;

b) selecting a desired length of the shelf-life of said pharmaceutical composition;

c) selecting a time at which an interim analysis will be performed;

d) selecting time points at which one or more measurements of one or more predetermined pharmaceutical test variables will be performed;

e) selecting a number of measurements of said predetermined test variables that will be performed at each of said time points;

f) selecting a value for the expected degradation rate of said pharmaceutical composition over time;

g) selecting a value for the intermediate precision of said measurements; and

h) selecting a probability level regarding the level of certainty of the outcome of said stability study;

i) calculating the shelf-life specification limits of said pharmaceutical composition based upon the variables selected in steps a) through h);

j) optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation; and

k) conducting a stability study for said pharmaceutical composition based on said optimized values selected for said pharmaceutical composition.

46. The method of claim 45 wherein the specification test limits are re-calculated by substituting in actual data obtained during said stability study for one or more of the variables selected in steps a) through h).

47. The method of claim 45 wherein said probability level regarding the level of certainty is at least 90%.

48. The method of claim 45 wherein the shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the probability level of said pharmaceutical composition satisfying its specification tests is at least 95%.

49. The method of claim 45 wherein the selected value of said expected degradation rate is based on previous long-term stability studies.

50. The method of claim 45 wherein said probability level is at least 95%.

51. The method of claim 45 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition in alternate formulations.

52. The method of claim 45 wherein the selected value of said expected degradation rate is based on previous accelerated stability studies of said pharmaceutical composition.

53. The method of claim 52 wherein the selected value is based on accelerated stability results that are temperature corrected by the Arrhenius formula.

54. The method of claim 45 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

55. The method of claim 45 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous accelerated stability studies of said pharmaceutical composition.

56. The method of claim 45 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from conducting a stability study of said pharmaceutical composition.

57. The method of claim 45 wherein the selected value of said expected degradation rate is based on conducting a stability study of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

58. The method of claim 45 wherein the time points for measurement of the variables selected in steps a) through h) are at 0, 3, 6, 9, and 12 months after start of the stability study of said pharmaceutical composition.

59. The method of claim 45 wherein the probable shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the

probability level of said pharmaceutical composition satisfying its specification tests is at least 95%.

60. The method of claim 45 wherein said pharmaceutical composition is administered through an oral administration of a pharmaceutical formulation such as a tablet.

61. The method of claim 60 wherein said tablet varies in physical size.

62. The method of claim 60 wherein the packaging for said pharmaceutical formulation varies.

63. The method of claim 60 wherein the dosage strength of an active ingredient in said tablet varies.

64. The method of claim 1 wherein in said analysis is an interim analysis.

65. The method of claim 64 wherein in said interim analysis is performed at least once.

66. The method of claim 1 further comprising selecting the number of batches of said pharmaceutical composition to be prepared is determined.

67. The method of claim 1 wherein at least one batch of said pharmaceutical composition is prepared.

68. The method of claim 67 wherein at least three batches of said pharmaceutical composition are prepared for testing in said stability study.

69. The method of claim 68 wherein said at least one batch of said pharmaceutical composition is tested for degradation.

70. The method of claim 24 further comprising selecting the number of batches of said pharmaceutical composition to be prepared is determined.

71. The method of claim 24 wherein at least one batch of said pharmaceutical composition is prepared.

72. The method of claim 71 wherein at least three batches of said pharmaceutical composition are prepared for testing in said stability study.

73. The method of claim 72 wherein said at least one batch of said pharmaceutical composition is tested for degradation.

74. The method of claim 45 further comprising selecting the number of batches of said pharmaceutical composition to be prepared is determined.

75. The method of claim 45 wherein at least one batch of said pharmaceutical composition is prepared.

76. The method of claim 75 wherein at least three batches of said pharmaceutical composition are prepared for testing in said stability study.

77. The method of claim 76 wherein said at least one batch of said pharmaceutical composition is tested for degradation.

78. The method of claim 24 wherein in said analysis is an interim analysis.

79. The method of claim 78 wherein in said interim analysis is performed at least once.

80. The method of claim 45 wherein in said analysis is an interim analysis.

81. The method of claim 80 wherein in said interim analysis is performed at least once.